

misleading. The statement represented and suggested that the estrogenic material present in the article consisted of estrogens as they naturally occur in and are extracted from pregnant mares' urine, whereas the estrogenic material present in the article did not consist of estrogens as they naturally occur in and are extracted from pregnant mares' urine.

Further misbranding, Section 502 (b) (1), the vials of the article bore no label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no label containing a statement of the quantity of the contents; Section 502 (e) (2), they bore no label containing the common or usual name of each active ingredient of the article; and, Section 502 (f) (1), the article bore no labeling containing directions for use.

DISPOSITION: June 10, 1948. A plea of guilty having been entered, the court imposed a fine of \$500.

**2404. Misbranding of Million Dollar Tonic. U. S. v. 212 Bottles \* \* \*.**  
(F. D. C. No. 24198. Sample No. 14105-K.)

**LIBEL FILED:** January 5, 1948, Northern District of Illinois.

**ALLEGED SHIPMENT:** On or about November 25, 1947, from Richmond, Ind., by the M. L. Carpenter Medicine Co. of Dublin, Ind.

**PRODUCT:** 212 bottles of *Million Dollar Tonic* at Chicago, Ill. Examination showed that the product was an aqueous solution of extracts of plant drugs, including aloe, preserved with a small proportion of a salicylate.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statements "Tonic \* \* \* If taken as an intestinal tonic" were false and misleading as applied to a product which was not capable of exerting a tonic effect upon the human body or of acting as a tonic to the intestines.

Further misbranding, Section 502 (f) (2), the article was essentially a laxative and its labeling failed to bear a warning to the effect that it should not be taken by persons suffering from nausea, vomiting, abdominal pain, or other symptom of appendicitis, and that frequent or continued use of the article or use of the article in accordance with the directions on the label may result in dependence upon laxatives to move the bowels.

DISPOSITION: May 27, 1948. Default decree of condemnation and destruction.

**2405. Misbranding of Bush Mulso Tablets, Sulpho, Bush Endo-Veg, Garlic-Parsley Tablets, and Bush Lemo Tabs. U. S. v. 150 Packages, etc. Tried to the court. Judgment for the Government. Decree of condemnation and destruction.** (F. D. C. No. 19364. Sample Nos. 35078-H to 35082-H, incl.)

**LIBEL FILED:** March 18, 1946, Eastern District of Missouri.

**ALLEGED SHIPMENT:** The *Bush Mulso Tablets* were shipped by the United Health Products Co., from Burbank, Calif., on or about February 18, 1946, and the *Sulpho* was shipped by Paso Robles Lab., from Los Angeles, Calif., on or about February 19, 1946. The other products were shipped by David V. Bush, from Gardena, Calif., on or about February 25, 1946.

**PRODUCT:** 150 packages of *Bush Mulso Tablets*, 95 bottles of *Sulpho*, 143 packages of *Bush Endo-Veg*, 24 dozen packages of *Garlic-Parsley Tablets*, and 16 dozen packages of *Bush Lemo Tabs* at St. Louis, Mo. The products were being sold in St. Louis by David V. Bush during the course of a series of so-called health lectures at which he offered these products for the treatment of various disease conditions.

**LABEL, IN PART:** "Bush Mulso Tablets \* \* \* Ingredients: Each tablet contains 6 grains of charcoal and ½ grain of papain combined in an inert base of malt diastase and a vegetable gum binder"; "Sulpho \* \* \* A Concentrate of Sulphur Mineral Hot Springs Water consisting essentially of the Polysulphides and Sulphides of Calcium and Sodium"; "Bush Endo-Veg \* \* \* Ingredients—Each tablet contains Pacific Ocean Kelp as a source of iodine in a base of desiccated alfalfa and celery, with excipients"; "Garlic-Parsley Tablets \* \* \* Each Tablet contains 3 grains of dehydrated Garlic and 3 grains of dehydrated Parsley with sugar, vegetable gums and artificial color as Tablet binders and coating"; and "Bush Lemo Tabs \* \* \* Ingredients—Vitamin C in a base of powdered lemon juice and corn syrup with excipients."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in those diseases, symptoms, and conditions for which the articles were offered in their advertising disseminated and sponsored by and on behalf of their manufacturer, packer, and

distributor. The *Bush Mulso Tablets* were offered for use in the prevention of neuritis, colitis, and cancer, for aiding vision and digestion, and for pimples, fluttering of the heart, shingles, tonsillitis, and stomach worms. The *Sulpho* was offered for use in the treatment of hemorrhoids, rheumatism, chronic rheumatism, gout, diphtheria, bronchitis, arthritis, and sleeplessness. The *Bush Endo-Veg* was offered for use to keep the thyroid gland and other endocrine glands in condition; to lengthen life; and to prevent flabby muscles, wrinkled face, flat chest, bulging abdomen, hernia, falling arches, varicose veins, double chin, high blood pressure, hardening of the arteries, headache, nausea from liver clogging, acne, skin eruptions, emotional disturbances, ringing in the ears, inferiority complex, menopausal disturbances, liver spots, derangement of the adrenal gland, weakness, stomach sickness, vomiting, abnormal kidney action, goiter, menstrual disorders, arthritis, overweight, watery eyes, and swelling of the feet. The *Garlic-Parsley Tablets* were offered for use in effecting longevity; in preventing calcification; in the treatment of nervous indigestion, cancer, and worms; and for cleansing the blood and eliminating pus from the body. The *Bush Lemo Tabs* were offered for use for pains in the body, driving the toxins of rheumatism and arthritis from the blood, tiredness, loss of appetite, shortness of breath, swelling of the legs, pale skin, bleeding, nosebleed, bleeding of the gums, anemia, ulcer of the stomach, nervousness, diabetes, mental disturbances, pernicious anemia, loss of weight and strength, heart and circulatory conditions, intestinal disorders, and high blood pressure; for keeping the eyes young; and for preventing impairment or loss of vision, loss of elasticity of the veins, colds, tonsillitis, skin blemishes, loosening of teeth, hardening of the arteries, and apoplexy.

**DISPOSITION:** David V. Bush of Mehoopany, Pa., appeared as claimant on or about April 8, 1946, and filed an answer denying that the products were misbranded as alleged in the libel. Thereafter, an application to intervene was filed on behalf of the National Dietary Food Association; and after a hearing in the matter the court, on or about February 3, 1947, ruled that the association should be permitted to intervene solely for the purpose of filing a memorandum in the case. A stipulation of facts which was agreed to by the Government and the claimant was filed on February 3, 1947. After consideration of the facts of the case and the briefs of the parties, the court, on July 11, 1947, handed down the following findings of fact and conclusions of law:

MOORE, *District Judge*:

#### FINDINGS OF FACT

"1. That the Marshal of this District, pursuant to Libel of Information filed in this cause, did, on March 20, 1946, seize:

67 packages of 'BUSH MULSO TABLETS,'  
36 bottles of 'SULPHO,'  
60 packages of 'BUSH ENDO-VEG,'  
12 dozen packages of 'GARLIC-PARSLEY TABLETS,'  
8 dozen packages of 'BUSH LEMO TABS,'

in the possession of David V. Bush at 2626 South Grand, St. Louis, Missouri, within the Eastern Division of Eastern Judicial District of Missouri.

"2. That the Marshal of this District did, on March 20, 1946, serve a copy of the said libel on David V. Bush, 2626 South Grand, St. Louis, Missouri, in whose possession the articles seized were found.

"3. That David V. Bush did file a verified claim of ownership to the articles seized in the cause herein.

"4. That the Claimant, David V. Bush, did file an Answer in the cause herein.

"5. That all of the said articles seized in the cause herein were shipped in interstate commerce from the State of California to St. Louis, in the State of Missouri.

"6. That David V. Bush was the packer and the distributor of the said articles of drug seized herein.

"7. That all of said articles seized herein were intended for use in the cure, mitigation, treatment, or prevention of disease in man or intended to affect the structure or function of the body of man and are, therefore, articles of drug under the Food, Drug and Cosmetic Act.

"8. That the label which appeared on the article of drug labeled in part 'Bush Mulso Tablets,' Libellant's Exhibit 1, was the label which appeared on each package of the said article of drug at the time that said drug was shipped in interstate commerce from Los Angeles, California, to St. Louis, Missouri, via Railway Express Agency, on or about February 19, 1946, and at the time that the said article of drug was seized in the cause herein.

"9. That the label on the individual packages of the article of drug labeled in part 'Bush Mulso Tablets' contains the statement: 'Directions: Three to six tablets after meals as required,' and the further statement: 'Provides the adsorbing properties of charcoal with the proteolytic enzymes or papain.'

"10. That there is no statement on the label of any disease or condition in man, or of the structure or other function of the body of man, informing the consumer when the directions 'Three to six tablets after meals as required' are to be followed.

"11. That the statement: 'Provides the adsorbing properties of charcoal with the proteolytic enzymes of papain' and the statement of the contents of the said article of drug, which also appears on the said label, do not inform the consumer of the use of the article of drug in the diagnosis, cure, mitigation, treatment, or prevention of any disease in man or the effect of the said article of drug upon any structure or any function of the body of man, or of any other use for the said article of drug.

"12. That the statement: 'Directions: Three to six tablets after meals as required,' suggests to the consumer that the said article of drug is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of some disease in man, or to have an effect upon some structure or some function of the body of man, but standing without a further statement as to its intended use, is misleading.

"13. That directions for use contained upon the label upon each package of the article of drug labeled in part 'Bush Mulso Tablets,' Libellant's Exhibit 1, are not adequate and do not inform the consumer of any use of the said drug.

"14. The label is misleading in view of the representation: 'Directions: Three to six tablets after meals as required,' in that it does not contain any statement as to the disease or condition in man or of the effect on the structure or body function for which the directions 'three to six tablets as required' are to be followed.

[Findings 15 to 27, inclusive, relate to "Bush Sulpho" and "Bush Endo-Veg" and are generally similar to those in paragraphs 8 to 14, inclusive, with reference to "Bush Mulso Tablets."]

"28. That the said label, which appeared on the article of drug, labeled in part 'GARLIC-PARSLEY TABLETS,' Libellant's Exhibit 4, was the label, which appeared on each package of the said article of drug at the time that the said article was shipped in interstate commerce from Gardena, California, to St. Louis, Missouri, via Railway Express Agency, on or about February 25th, 1946, and at the time that the said article of drug was seized in the cause herein.

"29. That the label on the individual packages of the article of drug, labeled in part 'GARLIC-PARSLEY TABLETS,' Libellant's Exhibit 4, contains the statement 'Each Tablet contains 3 grains of dehydrated Garlic and 3 grains of dehydrated Parsley with sugar, vegetable gums and artificial color as Tablet binders and coating. Suggested Use: For those persons wishing to include garlic and parsley in the regular diet, two of these tablets taken three times a day offers a convenient easy method. (No evidence of physiologic or therapeutic value.)'

"30. That there is no statement on the label of any disease or condition of man or of the structure or other functions of the body, for which the said article of drug is recommended as a diagnosis, cure, mitigation or treatment so as to inform the consumer when the directions 'two of these tablets taken three times a day' are to be followed.

"31. That the statement 'For those persons wishing to include garlic and parsley in the regular diet' does not inform the consumer of the said article of drug in the diagnosis, cure, mitigation or prevention of any disease in man or the effect of the said article of drug upon any structure or any function of the body of man or of any other use for the said article of drug.

"32. That as the said article is an article of drug, the said statement 'No evidence of physiologic or therapeutic value,' which may have been intended by the shipper to avoid the effect of the Food, Drug and Cosmetic Act, only

gives the consumer information that the said article has no use rather than states its intended use.

"33. That the statement of the 'Suggested Use' suggests to the consumer that the said article of drug is intended to be used in the diagnosis, cure, mitigation, treatment or prevention of some disease in man or to have an effect upon some structure or some function of the body of man, but standing without further statement as to its intended use is not adequate directions for use and is misleading.

"34. That the directions for use contained on the label upon each package of the article labeled in part 'GARLIC-PARSLEY TABLETS,' Libelant's Exhibit 4, do not inform the consumer of the use of said drug and therefore are not adequate directions for use.

"35. That the label is misleading and does not contain adequate directions for use in view of the representation 'Suggested Use: For those persons wishing to include garlic and parsley in the regular diet, two of these tablets taken three times a day, offers a convenient easy method.' in that it does not contain any statement as to the disease or condition in man or the effect upon the structure or any function of the body of man for which the said article of drug is a diagnosis, cure, mitigation or treatment, and for which two of these tablets three times a day are to be followed.

"36. That the said label, which appeared on the article of drug 'BUSH LEMO TABS,' Libelant's Exhibit 5, was the label, which appeared on each package of the article of drug at the time that said article of drug was shipped in interstate commerce from Gardena, California, to St. Louis, Missouri, via Railway Express Agency on or about February 25th, 1946, and at the time that the said article of drug was seized in the cause herein; that the label on the individual packages of the article of drug labeled in part 'BUSH LEMO TABS' contains the statement 'A SPECIAL DIETARY SOURCE OF VITAMIN C SUGGESTED USE—One to two tablets daily. Tablets may be chewed or swallowed with water. Each tablet provides the adult with the minimum daily requirements of Vitamin C and the child with 1½ times the minimum requirements.'; that there is no statement on the label of any disease or condition in man or the structure or other function of the body of man for which the said article of drug is a diagnosis, cure, mitigation or treatment, so as to inform the consumer when the directions 'One to two tablets daily' are to be followed.

"37. That the statement 'A SPECIAL DIETARY SOURCE OF VITAMIN C' and 'Each tablet provides the adult with the minimum daily requirements of Vitamin C and the child with 1½ times the minimum requirements' do not inform the consumer of the use of the said article of drug in the diagnosis, cure, mitigation, treatment or prevention of any disease in man, or the effect of the said article of drug upon any structure or any function of the body of man or any other use for the said article of drug.

"38. That the statement 'SUGGESTED USE—One to two tablets daily' suggest to the consumer that the said article of drug is intended to be used in the diagnosis, cure, mitigation, treatment or prevention of any disease in man or to have an effect upon some structure or some function of the body of man, but standing without any further statement as to its intended use, the said label does not contain adequate directions for use and is misleading.

"39. That the directions for use contained upon said label upon each package of the drug labeled in part 'BUSH LEMO TABS,' Libelant's Exhibit 5, do not inform the consumer of any use of the said drug and are therefore inadequate directions for use.

"40. That the label does not contain adequate directions for use and is misleading in view of the representation 'SUGGESTED USE—One to two tablets daily,' and that the said label does not contain any statement of the disease or condition in man or the effect upon the structure or body function for which the directions 'One to two tablets daily' are to be followed.

#### CONCLUSIONS OF LAW

"1. That each of the said articles of drug were introduced into and were shipped in interstate commerce from California to St. Louis, Missouri.

"2. That the said articles of drug, seized in the cause herein, were intended for use in the cure, mitigation, treatment or prevention of the disease in man, or intended to affect the structure or function of the body of man, and are therefore articles of drug under the Federal Food, Drug and Cosmetic Act of 1938, as amended (21 U. S. C. A. 321 (g)).

"3. A drug is misbranded unless its labeling bears 'adequate directions for use' (21 U. S. C. A., Section 352 (f)).

"4. The requirement that the labeling bear 'adequate directions for use' requires not only that the labeling bear statement of the dosage or the amount, which is recommended that the consumer use, but also a statement of the purpose, namely, the disease or the effect upon the structure or function of the body for which the article of drug is to be taken.

"5. That directions for use are not adequate unless the purpose for which the drug is to be taken, as well as the amount to be taken, appear on the labeling.

"6. That the labels on the five articles of drug seized herein do not bear a statement of the disease or of the effect on the structure or function of the body of man, for which the said articles of drug are to be used, and therefore the labeling does not bear adequate directions for use.

"7. That the labeling is misleading.

"8. That the said articles of drug seized herein are misbranded.

"9. That the said articles of drug seized herein are subject to forfeiture and condemnation to the United States.

"10. Because of the facts heretofore found, libelant is entitled to a decree of condemnation and forfeiture.

"11. That the articles of drug seized herein were seized in the Eastern Judicial District, Eastern Division, of Missouri, and that the Court has jurisdiction over this cause by virtue of Section 334, Title 21, U. S. C. A.

"12. That as no showing has been made that the said articles of drug seized herein have any value or can be sold without violating the Federal Food, Drug and Cosmetic Act, and any State or local law, the said articles of drug shall be destroyed by the United States Marshal.

"13. Libelant is entitled to its costs herein.

"14. Under the facts heretofore found and the law, it is not necessary to pass upon the validity of the regulation, 2.106a1, of the Administrator of the Food and Drug Administration, or to make any findings of fact as to the advertising disseminated by the claimant herein, or to determine the customary conditions of purchase and use of the said articles of drug."

In accordance with the above findings and conclusions, a decree was entered on July 11, 1947, forfeiting the products to the United States and directing that they be destroyed. On July 21, 1947, the claimant filed a motion for a new trial and to amend the findings of fact and conclusions of law. After considering the briefs of the parties, the court, on March 23, 1948, overruled the claimant's motion for a new trial; and on August 4, 1948, the court ordered that the decree for destruction of the products be executed.

**2406. Misbranding of pile pipes. U. S. v. 702 \* \* \*. (F. D. C. No. 24347. Sample No. 26662-K.)**

**LIBEL FILED:** February 17, 1948, Eastern District of Missouri.

**ALLEGED SHIPMENT:** On or about July 18, 1946, by the Victor Metal Products Corp., from Brooklyn, N. Y.

**PRODUCT:** 702 *pile pipes* at St. Louis, Mo. Examination showed that the pipes were plastic tubes which were threaded at one end to attach to collapsible tubes of ointment.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

**DISPOSITION:** March 18, 1948. Default decree of condemnation and destruction.

#### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS**

**2407. Adulteration and misbranding of Gaduplex and Vibeta Elixir with Iron. U. S. v. Columbus Pharmacal Co., Freeman A. Rostofer, and Robert N. Fullerton. Pleas of guilty. Fine of \$600 against each defendant. (F. D. C. No. 24267. Sample Nos. 53833-H, 83283-H.)**

**INFORMATION FILED.** June 15, 1948, Southern District of Ohio, against the Columbus Pharmacal Co., a corporation, Columbus, Ohio, and Freeman A. Rostofer, president, and Robert N. Fullerton, vice-president.

**ALLEGED SHIPMENT:** On or about December 18, 1946, and July 14, 1947, from the State of Ohio into the State of Kentucky.